IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
CENTRAL DIVISION

ABBOTT GMBH & CO., KG, ABBOTT BIORESEARCH CENTER, INC., AND ABBOTT BIOTECHNOLOGY LTD., Plaintiffs, vs. CENTOCOR ORTHO BIOTECH, INC., AND CENTOCOR BIOLOGICS, LLC, Defendants.	Civil Action No. 4:09-cv-11340-FDS **Jury Trial Demanded**

DEFENDANTS' RESPONSE TO PLAINTIFFS' MOTION FOR A PROTECTIVE ORDER

I. SUMMARY OF CENTOCOR'S RESPONSE

Abbott's[1] request to delay discovery concerning injunction-related issues is entirely inconsistent with its request for this extraordinary relief. Although Abbott argues that such discovery, if taken now, may become "out of date," Abbott has failed to provide any indication or support for how this would be the case. With no temporal limit on the time period in which Abbott must prove the factors demonstrating that it is entitled to injunctive relief, Abbott should have at least provided the current basis for its injunction claim. But Abbott's refusal to provide even such basic information indicates not only that there is no urgency to its request for injunctive relief, but also that its claim is baseless.

The accused product in this case – Stelara® – is an anti-IL12 antibody. At the time Abbott filed its complaint, Abbott was seeking FDA approval to sell its own anti-IL12 antibody product. But, within the last few months, Abbott withdrew its application for FDA approval after the FDA raised issues relating to certain safety studies. Abbott would likely prefer to wait to see if it will ever be in a position to pursue approval of an anti-IL-12 antibody before laying out its position on its request for an injunction. But that "wait and see" approach is inconsistent with the magnitude of the relief requested, and Centocor[2] should not be subjected to this continued threat under the present circumstances. The Court could, and should, deny Abbott's request for a permanent injunction based on Abbott's failure to timely provide discovery supporting its request for this relief.

But, if Abbott is to be given a pass on providing this discovery now, then Centocor would not oppose resetting the time for injunction-related discovery so that it occurs "after a

[1] "Abbott" refers collectively to Abbott GmbH & Co., KG, Abbott Bioresearch Center, Inc. and Abbott Biotechnology Ltd.

[2] "Centocor" refers collectively to defendants Centocor Ortho Biotech, Inc. and Centocor Biologics LLC.

determination has been made concerning Centocor's liability for infringement of the asserted Abbott patents," as Abbott now suggests (Abbott Br. at 1). And, to be fair to Centocor, under the present circumstances, the schedule should be set so that such discovery would not be undertaken until after both the infringement action and the 146 action have been tried and any related appeals completed. If judicial efficiency and economy in discovery are Abbott's primary goals, then this is the only way to fully satisfy those purposes.

II. FACTUAL BACKGROUND

Centocor's Stelara product is a highly successful anti-IL-12 antibody therapy that was approved for sale by the FDA in September 2009 for the treatment of moderate to severe plaque psoriasis (Ex. 1, Stelara Approved Label). Psoriasis is caused by a patient's overactive immune system that triggers the body to grow skin cells up to ten times faster than normal. (See Stelara Information Website, Understanding Psoriasis, available at http://www.stelarainfo.com/stelara-psoriasis/understanding-psoriasis). These skins cells pile up on the surface of the skin and form red patches or lesions called plaques. (*Id*.). Psoriasis can be both physically painful and psychologically damaging to those it affects.

Stelara is the first and only anti-IL-12 antibody product to be approved for sale in the United States. To date, Stelara has been used to treat thousands of patients, many of whom do not respond to other available therapies.

Although Abbott has been trying to develop its own anti-IL-12 antibody, it recently withdrew the application it filed with the FDA seeking approval to market its anti-IL-12 antibody (Ex. 2, SEC filing Form 8-K dated January 14, 2011). This action was a result of the FDA's request for further studies relating to the drug's safety. (See *id.*, Ex. 3, Cure Now Article).

III. ARGUMENT IN RESPONSE

Since the inception of this litigation, Abbott has been seeking the extraordinary remedy of a permanent injunction. Not surprisingly, Centocor has been seeking discovery concerning the bases for this request. Abbott has never suggested that the discovery sought by Centocor on this subject matter is irrelevant. Abbott has simply taken the position that it does not need to provide this discovery until sometime after fact discovery closed in this case.

Abbott's approach posed a serious problem for Centocor. The Court-ordered fact discovery deadline did not carve out a separate time period for injunction-related discovery. Centocor does not know when (if at all) the Court might expect to substantively consider the merits of Abbott's request for an injunction. And Centocor did not want to be in a position where it risked being denied discovery needed to defend against this serious claim because it failed to take that discovery within the Court-ordered deadline.

But because the discovery related to an issue on which Abbott bears the burden of proof, and Abbott was not objecting to providing the discovery (at some later, unspecified, time), it was Abbott's burden to take some action to postpone the time for providing relevant information. Centocor suggested that Abbott had the option of approaching the Court to request a separate discovery period for injunction-related issues or filing a motion for a protective order. Abbott decided to do the latter, and did so in the last week of fact discovery.

A. Centocor's 30(b)(6) Notice Seeks Relevant Discovery

Centocor served a Rule 30(b)(6) Notice for Deposition of Abbott on September 3, 2010 that included Topics 43-45. These topics sought, *inter alia*, Abbott's ***factual*** basis for alleging that it is entitled to a permanent injunction.[3] Abbott never denied that the discovery sought by

[3] The topics specifically seek "[t]he evidence and factual basis of Abbott's contention that Abbott will suffer severe and irreparable harm unless Centocor's infringement is enjoined by this Court and documents reflecting the same"

Centocor was relevant, but it would never commit to providing the requested information (Ex. B to Abbott's Br.).

In January, Centocor followed up on its request for a deponent on this subject matter, but that was ignored by Abbott (Ex. D to Abbott's Br.). Centocor wrote to Abbott again on February 16, reiterating its request for a Rule 30(b)(6) witness on Topics 43-45 (Ex. 4, Letter from M. Pearson to V. Watson). Then, on February 17, with less than two weeks left before the fact discovery deadline, Centocor advised Abbott that it had to either produce a witness on Topics 43-45 or move the Court so that Centocor could preserve its right to take the discovery sought (Ex. E to Abbott's Br.). It was not until February 21 that Abbott finally relayed its intent to seek a protective order (Ex. G to Abbott's Br.).

B. Abbott's Request To Delay Discovery Should Be Applied Consistently

Abbott has not argued that the requested discovery is irrelevant, but instead takes the position that it is untimely and premature because any discovery on the issue of an injunction should take place only if Abbott were to prevail on the issue of infringement at trial (Abbott Br. at 4-5). There have been several recent telephonic status conferences with the Court where scheduling was discussed, and Abbott could have raised this issue about the timing of this discovery, but Abbott failed to even mention it.

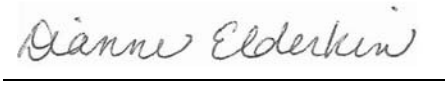
Centocor should not be faced with the continued threat of an injunction under the present circumstances. But, if the time is to be reset for this discovery, it should be deferred until "after a determination has been made concerning Centocor's liability for infringement of the asserted Abbott patents" (Abbott Br. at 1) – meaning, after both the infringement action and the 146

(Topic 43); "[t]he evidence and factual basis of Abbott's contention that Abbott has suffered, and will continue to suffer, substantial damages and documents reflecting the same" (Topic 44); and "[t]he evidence and factual basis of Abbott's contention that it is entitled to a permanent injunction and documents reflecting the same" (Topic 45) (Ex. A to Abbott's Br.)

action have been tried and any related appeals completed. That would, in fact, be the approach most consistent with Abbott's concerns about saving time and resources, and ensuring that any testimony and opinions on the issue are "not out of date " (Abbott's Br. at 4-5).

IV. CONCLUSION

For the foregoing reasons, Abbott's motion for a protective order and Abbott's request for a permanent injunction should be denied based on Abbott's failure to timely provide relevant discovery concerning the bases for pursuing this relief. Alternatively, Centocor requests that the Court order that all discovery relating to whether Abbott is entitled to an injunction be postponed until after the infringement and 146 actions, and all related appeals, have been completed.

Date: March 11, 2011 By: 

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Defendants' Response to Plaintiffs' Motion for a Protective Order was electronically mailed to the following counsel of record on March 11, 2011 through the Court's ECF notification system.

Angela Verrecchio